UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,557	01/23/2006	Russell J. Thomas	283569US0PCT	2098

22850 7590 09/20/2007

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
LOEWE, SUN JAE Y	
ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
09/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/565,557	THOMAS ET AL.	
	Examiner	Art Unit	
	Sun Jae Y. Loewe	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,10,11,15-18 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10,11 and 15-18* is/are allowed.

6)☒ Claim(s) *1,3,4,6 and 28* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4, 6, 10, 11, 15-18 and 28 are pending in the instant application. Claims 5, 7-9, 12-14 and 19-27 were cancelled by amendment filed on July 25, 2007.

Response to Amendment

2. Applicant's amendment and arguments/remarks were fully considered. The 35 USC 112 1st paragraph rejections (written description and enablement) set forth in the previous office action are withdrawn.

Rejoinder

3. Claims 10, 11, 15-18 directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(b), claims 1-4, 6 and 28 directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between groups I-III as set forth in the Office action mailed on March 1, 2007 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Objections

4. Claim 2 objected to for being dependent on a base rejected claim, but would be allowable if rewritten in independent form.

5. Claims 1, 3, 6, 10, 11 and 18 objected to because it is not written in proper Markush format. The claims recite:

"R^3 is selected from the group consisting of: ..... an amino group, or (ii) a cyclopentyl group, ..."

Pursuant MPEP 803.02, the claims should read "... and amino group and (ii)..". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 4, 6 and 28 rejected under 35 U.S.C. 112, first paragraph. The specification is enabling for the method of treating diabetes type II and obesity (eg. Asante-Appiah et al., abstract). The specification does not reasonably provide enablement for the method of treating diseases other than diabetes type II and obesity. Furthermore, the specification does not provide enablement for the method of preventing the claimed diseases. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8USPQ2s 1400, 1404 (Fed. Cir. 1988). MPEP 2164.01(a) states "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue". The factors are applied below to the instant claims.

The breadth of the claims
The claims are drawn to method of treatment and prevention of disease that include, for example, diabetes (type I and type II), obesity, hyperlipidemia.

The nature of the invention
Support for the intended use is based solely on the PTP1B inhibition activity of the instantly claimed compounds.

The state of the prior art/level of ordinary skill/level of predictability
The level of ordinary skill is high, however, the level of predictability in the art of treating/preventing the claimed diseases is low. The state of the art is described by the following:

- Surgery and medicines do not work by themselves to treat/prevent/cure obesity (http://www.webmd.com/diet/tc/Obesity-Overview).
- It is not possible to reduce certain risk factors associated with diabetes type II: eg. age, family history, ethnicity. Other risk factors may be reduced by a combination of physical activity, healthier eating, and possibly medication (http://diabetes.webmd.com/guide/preventing-type-2-diabetes). *Conclusion:* diabetes type II cannot be prevented by medication alone.
- Hyperlipidemia: it is necessary to first identify and treat any potential underlying medical problems, eg. diabetes, hypothyroidism. Treatment itself includes dietary changes, weight reduction and exercise (http://www.healthscout.com/ency/68/366/main.html). Different types of hyperlipidemia are treated by different medications,

none of which involve the etiological pathway of PTP1B inhibition (http://en.wikipedia.org/wiki/Hyperlipidemia). *Conclusion*: it is unpredictable to treat hyperlipidemia via etiological pathways that are not known in the art, eg. PTP1B inhibition. Medication alone (via any etiological pathway) is unlikely to prevent hyperlipidemia.

- Diabetes Type I: cannot be prevented; currently available method of treatment does not involve inhibition PTP1B (http://health.yahoo.com/topic/diabetes/overview/article/healthwise/hw34305).

There is no art recognized correlation between PTP1B inhibition and the prevention of any disease claimed. Furthermore, the claimed diseases are not known to be preventable by any other etiological pathway, ie. pathways that do not involve PTP1B inhibition.

The amount of direction provided by the inventor/existence of working examples
No direction or working examples

The quantity of experimentation needed to make or use the invention
In the absence of guidance and/or a correlation between PTP1B inhibition and treatment/prevention of the claimed diseases, in view of the high degree of unpredictability, one of ordinary skill is not enabled to practice the claimed invention. The amount of experimentation is deemed to be undue.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites: "A method of treating or preventing ... appetite regulation". It is unclear how "appetite regulation" can be treated or prevented. Moreover, if this limitation is interpreted to mean "a method of appetite regulation", it is still unclear what the claim boundaries are (eg.

decrease appetite, increase appetite, decrease and increase appetite). Appropriate clarification/correction is required.

For the reasons described above, the limitation " A method of treating or preventing ... appetite regulation" was not examined herein.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sun Jae Y. Loewe
Art Unit 1626

REBECCA ANDERSON
PRIMARY EXAMINER